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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,891	02/04/2000	Hermann Kuenzer	SCH-1692	8032
23599	7590	09/10/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			QAZI, SABIHA NAIM	
		ART UNIT	PAPER NUMBER	
		1616		

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/497,891	KUENZER ET AL.
	<b>Examiner</b> Sabiha Qazi	<b>Art Unit</b> 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 June 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 53-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 53-65 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)              |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.  |

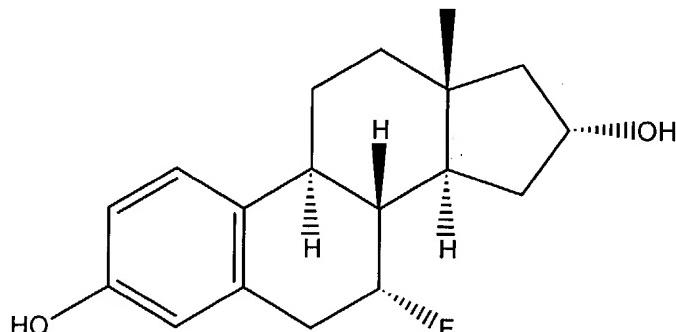
**Final Office Action**

Acknowledgement is made of the response filed on 6/14/04. Amendments are entered.

Claims 53-65 are pending. No claim is allowed.

Rejection under 102 (b) is withdrawn because claims are amended to overcome the rejection. Rejection under 112 (1st) is maintained because arguments are not found persuasive. Applicants have cited In re Johnson, 194 USPQ 187 (CCPA 1977), however, example 31 and 32 are not the same as the compounds 16 ethinyl-estra compounds disclaimed. Examples 1 and 2 are correct and can be excluded. Examiner note, that rejection has been made over ethinyl compounds.

Elected species



7-alpha-fluoro-estra-1,3,5(10)-triene-3,16alpha diol

Elected species is allowable.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 53-65 rejected under 35 U.S.C. 103(a) as being unpatentable over ARUNACHALAM et al. (Journal of Biological Chemistry, 254(13), 5900-5, 1979).

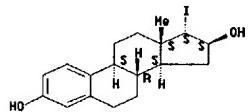
ARUNACHALAM et al. teaches 3, 16-dihydroxyestra-1,3,5(10)-trienes which embrace Applicant's claimed invention (see page 5905 ; compounds 19a-c, the compounds of the following RNs: 71683-63-1, 71683-69-7, and 71683-70-0).

1. RN 71683-63-1 CAPLUS

CN Estra-1,3,5(10)-triene-3,16-diol, 17-iodo-,

Absolute stereochemistry.

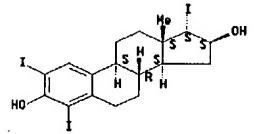
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2. RN 71683-69-7 CAPLUS

CN Estra-1,3,5(10)-triene-3,16-diol, 2,4,17-triiodo-, (16<SYM98>,17<SYM97>)-

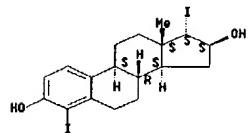
Absolute stereochemistry.



3. RN 71683-70-0 CAPLUS

CN Estra-1,3,5(10)-triene-3,16-diol, 4,17-diido-, (16<SYM98>,17<SYM97>)-

Absolute stereochemistry.



Instant claims differ from the reference in claiming a broader scope of 16alpha hydroxyestra compounds. The difference is: at R17, Applicants' are claiming fluoro atom

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whereas prior art teaches iodo atom. Both iodine and fluorine belong to the same periodic group; the same results are expected.

It would have been obvious to one skilled in the art at the time of invention to prepare the presently claimed invention because ARUNACHALAM et al. teaches the iodo group at 17 position. One skilled in the art would be motivated to prepare another similar compound with any halogen atom such as presently claimed fluro because both iodine and fluorine belong to the same periodic group (Group VII).

In absence of any criticality and/or unexpected results, presently claimed invention is *considered prima facie* obvious over the prior art of record.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

**Claim Rejections - 35 USC § 112**

Claims 53-65 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The proviso to disclaim the compounds 16a-ethinylestra1,3,5(10)-triene-3,16a-diol and 16a-ethinylestra1,3,5(10)-triene-3,16a-diol is considered new matter because these compounds were not disclaimed in original claims.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

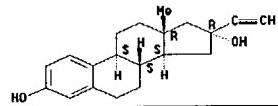
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53-65 are rejected under 35 U.S.C. 102(b) as being anticipated by AN 1979:66957 CAPLUS (OJASOO et al), and AN 1970:3637 CAPLUS (ROUSSEL-UCLAF). The references disclose this compound.

RN 24989-47-7 CAPLUS

CN Estra-1,3,5(10)-triene-3,16-diol, 16-ethynyl-, (16<SYM97>)- (9CI) (CA INDEX  
NAME)

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### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D  
PRIMARY EXAMINER

Saturday, September 4, 2004